### 510(k) Summary of Safety and Effectiveness Prepared in accordance with 21 CFR Part 807.92

JAN 1 8 2013

#### Section a):

### 1. Submitter's contact name, address, telephone/fax number

Angela Van Arsdale RA/QA Manager Hitachi Aloka Medical, Ltd., 10 Fairfield Boulevard Wallingford, CT 06492 Tel: (203)269-5088 Ext. 346

Fax: 203-269-6075

Date Prepared: 12/10/2012

2. <u>Device Name:</u> Prosound F75 Diagnostic Ultrasound System

90 IYN - Ultrasonic Pulsed Doppler Imaging System 21 CFR 892.1550 90 ITX - Transducer Ultrasonic, Diagnostic 21 CFR 892.1570

90 IYO - Ultrasonic Pulsed Echo Imaging System 21 CFR 892.1560

### 3. Substantially Equivalent Devices:

Aloka Prosound F75 Diagnostic Ultrasound System, (K110207), for system & probes. Aloka SSD-5000 V 5.0 Ultrasound System, (K033311), for expanded indications. Aloka SSD-5500 V6.0 Diagnostic Ultrasound System, (K032875), for expanded indications.

### 4. Device Description:

The Prosound F75, formerly named Aloka Prosound F75, Diagnostic Ultrasound System is a full feature imaging and analysis system. It consist of a mobile console that provides acquisition, processing and display capability. The user interface includes a computer type keyboard, specialized controls and a display. The changes made to the Prosound F75 are the expanded indications: Adult/ Pediatric Cardiac- TEE, Neonatal/Pediatric, Cardiac, Intra-operative Neurosurgery, and Trans-esoph (non-cardiac).

#### 5. Indications for Use:

The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Intra-operative; Intra-operative (Neurosurgery); Pediatric; Small Organ; Neonatal Cephalic; Trans-rectal; Trans-vaginal; TEE (non-cardiac); Musculo-skeletal; Cardiac Adult; Cardiac, Adult -TEE; Cardiac - Neonatal; Cardiac - Pediatric; Cardiac Pediatric, TEE; Peripheral Vascular; and Gynecological applications. The device is not indicated for Ophthalmic applications.

### 6. Comparison w/ Predicate Device:

The Prosound F75 with expanded indications is technically comparable and substantially equivalent to the current Aloka Prosound F75 (K110207) and to the above mentioned predicates. They are Track 3 systems that employ the same fundamental and scientific technology.

### 510(k) Summary of Safety and Effectiveness Prepared in accordance with 21 CFR Part 807.92

### Section b):

#### 1. Non-clinical Tests:

No new hazards were identified with the addition of the added Indications. The clinical safety and effectiveness of the system and transducers have been identified in the previous Aloka Prosound F75 submission (K110207), with the above predicates as well as this submission. The clinical safety and effectiveness of the added indications are well accepted for use with ultrasound systems including the predicate device, Aloka Prosound F75 (K110207).

The device and its transducers have been evaluated for acoustic output, biocompatibility, cleaning & disinfection effectiveness, electromagnetic compatibility, as well as electrical and mechanical safety, and have been found to conform with applicable medical device safety standards.

### 2. Clinical Tests: None Required.

### 3 Conclusion:

The Hitachi-Aloka Medical, Ltd.'s Prosound F75 with expanded indications is substantially equivalent in safety and effectiveness to the predicates identified above;

- The predicate device(s) and the Prosound F75 with expanded indications are indicated for diagnostic ultrasound imaging and fluid flow analysis,
- The predicate device(s) and the Prosound F75 with expanded indications have the same gray scale and Doppler capabilities,
- The predicate device(s) and the Prosound F75 with expanded indications use essentially the same technologies for imaging, Doppler functions and signal processing,
- The predicate device(s) and the Prosound F75 with expanded indications have acoustic output levels below the Track 3 FDA limits,
- The predicate device(s) and the Prosound F75 with expanded indications are manufactured under equivalent quality and manufacturing systems,
- The predicate device(s) and the Prosound F75 with expanded indications are manufactured of materials equivalent bio safety. The materials have been evaluated and found to be safe for this application,
- The predicate device(s) and the Prosound F75 with expanded indications are designed and manufactured to the same electrical and physical safety standards.

Note: The Hitachi-Aloka Medical, Ltd. Ultra-Sound System naming convention for this device can be identified as Aloka Prosound F75 or Prosound F75; both trade names reference the same device. The trade name, Aloka Prosound F75, listed within K110207 was modified to Prosound F75 prior to this premarket 510(K) submission and may be identified as "Prosound F75, formerly named Aloka Prosound F75" within the text of this submission. All the device instruction and operator manuals, advertisement and promotional materials, and labeling will identify the device as Prosound F75. The naming convention change is simply a marketing decision and not indicative of a separate device or any design modifications other than the modifications described with the body of this submission.



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-002

January 18, 2013

Hitachi Aloka Medical, Ltd. c/o Ms. Angela Van Arsdale RA/QA Manager 10 Fairfield Blvd. WALLINGFORD CT 06492

Re: K123828

Trade/Device Name: Prosound F75 Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, ITX, and IYO

Dated: December 10, 2012 Received: December 12, 2012

#### Dear Ms. Arsdale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the Prosound F75 and the following transducers intended for use with the Prosound F75 Ultrasonic pulsed Doppler Imaging System, as described in your premarket notification:

<u>Transducer N</u>	<u>Model Number</u>	
<u>UST-5293-5</u>	<u>UST-9130</u>	UST-52114P
<u>UST-5411</u>	<u>UST-9132 I &amp; T</u>	UST-52119S
<u>UST-5415</u>	<u>UST-9133</u>	UST-52121S
<u>UST-5417</u>	<u>UST-9135P</u>	UST-52124
<u>UST-5419</u>	UST-9146 I & T	GF-UE160 AL5
<u>UST-5713T</u>	<u>UST-9147</u>	GF-UCT180
<u>UST-9115-5</u>	<u>UST-52105</u>	BF-UC180F
<u>UST-9118</u> ·	<u>UST-52110S</u>	TGF-UC180
<u>UST-9120</u>	<u>UST-52120S</u>	
	UST-5293-5 UST-5411 UST-5415 UST-5417 UST-5419 UST-5713T UST-9115-5 UST-9118	UST-5411       UST-9132 I & T         UST-5415       UST-9133         UST-5417       UST-9135P         UST-5419       UST-9146 I & T         UST-5713T       UST-9147         UST-9115-5       UST-52105         UST-9118       UST-52110S

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <a href="http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm">http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm</a> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <a href="http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm">http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm</a>.

Sincerely yours,

Sean M. Boyd -S

or

Janine Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

510(K) Number (if known):

# Indications for Use

Device Name:	Prosound F75		
Indications For Use:		•	
	evaluation of Feta (Neurosurgery); Pedi Trans-vaginal; TEE Cardiac, Adult –TEE Pediatric, TEE; Perip	led for use by a qualified p al; Abdominal; Intra-opera atric; Small Organ; Neonatal E (non-cardiac); Musculo-s Cardiac - Neonatal; Cardi pheral Vascular; and Gynecol cated for Ophthalmic applicat	tive; Intra-operative Cephalic; Trans-rectal; keletal; Cardiac Adult; ac - Pediatric; Cardiac ogical applications.
Prescription Use √ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The Counter Use_ (21 CFR 801 Subpart C)	
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Concurrence of CDRH, Office of Device Evaluation Sean M. Boyd -S

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Division of Radiological Health

lice of in Vitro Diagnostics and Radiological Hei

System: Prosound F75

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application		<del></del>			of Operation	- 10110 N.D.	
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P		P	Note I	
i L	Abdominal	P	P	P		P	Note 1	
iL	Intra-operative (Specify)*	P	P	P		P	Note 1	
	Intra-operative (Neurosurgery)	N	N	N		N	Note 1	
	Laparoscopic			,				
1 L	Pediatric	N	N	N		N		
	Small Organ (Specify)*	Р	P	. P	N	Р	Note 1,2	
Fetal	Neonatal Cephalic	P	Р	·P		P	Note 1	
Imaging & Other	Adult Cephalic	·						
Oulei	Trans-rectal	P	P	P		P	Note 1	
	Trans-vaginal	Р	P	P		P	Note 1	
	TEE (non cardiac)	N	N	N		N	Note 1	
	Musculo-skeletal (Convent.)	P	P	P		P	Note 1	
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
	Cardiac, Adult	P	P	P	P	P	Note 1, 2	
	Cardiac Adult, TEE	N	N	N	N	N	Note 1, 2	
L	Cardiac- Neonatal	N	N	N	N	N	Note 1, 2	-
Cardiac	Cardiac- Pediatric	N	N	N	N	N	Note 1, 2	
	Cardiac Pediatric, TEE	N	N	N	N	N	Note 1, 2	
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral	Peripheral Vascular	P	P	P	N	P	Note 1,2	
Vessel	Other: Gynecological	P	Р	P		P	Note 1	_

N = new indication; P= previously cleared by FDA-(K110207); E=added under Appendix E

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

Note 3: Specification for "Other" Airways, Tracheobronchial tree, Gastrointestinal Tract and Surrounding Organs

\*Applications: Small Parts - (breast, testes, & thyroid...), Intra-operative - (liver, pancreas, gall bladder...)

Other:

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Prescription Use (Per 21 CFR 801.109)

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Office of In Vitro Diagnostics and Radiological Health

510(k) 1/23828

System: Prosound F75 Transducer: UST-567

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application					of Operation		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
·	Fetal							
	Abdominal							
	Intra-operative (Specify)				·			
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
Fetal Imaging	Small Organ (Specify)*	P	P	P		P	See note 1	
& Other	Neonatal Cephalic							
	Adult Cephalic							
<u> </u>	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
1	Musculo-skeletal (Convent.)	P	P	Р	-	P	See note 1	
	Musculo-skeletal (Superficial)							
	Intravascular							
<u> </u>	Intra-luminal							
	Cardiac Adult							
<u> </u>	Cardiac Adult, TEE							
Cardiac	Cardiac- Neonatal			-				1
L	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral	Peripheral Vascular ·	P	Р	P		P	See note 1	
Vessel	Other: Gynecological							

P= previously cleared by FDA-(K110207)

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

Other:

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<sup>\*</sup>Applications: Small Parts - (breast, testes, & thyroid...), Intra-operative - (liver, pancreas, gall bladder...)

System: <u>Prosound F75</u> Transducer: UST-675P

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application		-		•	of Operation		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal					,		•
	Intra-operative (Specify)						_	ļ
	Intra-operative (Neuro)		<u> </u>					
	Laparoscopic							
	Pediatric		1					·
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	See note 1	
	Trans-vaginal	P	P	P		P	See note 1	
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal							
٠.	(Superficial)		<u> </u>					
	Intravascular							
	Intra-luminal							
	Cardiac Adult							
a . I	Cardiac Adult, TEE							
Cardiac	Cardiac- Neonatal	_	<u> </u>					<u> </u>
L	Cardiac Pediatric, TEE		<u> </u>					
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral	Peripheral Vascular							
Vessel	Other: Gynecological				1			

P= previously cleared by FDA- (K110207)

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Sean M. Boyd -S

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Division of Radiological Health

System: Prosound F75 Transducer: UST-677P

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application		<del>'</del>			of Operation		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic .							
	Fetal							
	Abdominal							
	Intra-operative (Specify)							
[	Intra-operative (Neuro)			* '				
	Laparoscopic					:	·	
	Pediatric				,			
Fetal Imaging	Small Organ (Specify)					İ		
& Other	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Е	Е	Е		E		
	Trans-vaginal		•					
	Trans-urethral							
ĺ	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal							
ļ	(Superficial)							
Ĺ	Intravascular							
	Intra-luminal	· ·						
į.	Cardiac Adult							
, . I	Cardiac Adult, TEE							
Cardiac	Cardiac- Neonatal	'						<u> </u>
	Cardiac Pediatric, TEE							
Į.	Intravascular (Cardiac)			<u> </u>				
	Other (Specify)							
Peripheral	Peripheral Vascular						•	
Vessel	Other: Gynecological							

E=added under Appendix E

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

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Prescription Use (Per 21 CFR 801.109)

Division of Radiological Health

System: <u>Prosound F75</u> Transducer: UST-678

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application					of Operation		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							, , , , ,
	Fetal							
	Abdominal			-	•	,		
	Intra-operative (Specify)							
	Intra-operative (Neuro)					•		
	Laparoscopic							
	Pediatric							
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic							
	Adult Cephalic	-						
	Trans-rectal	E	E	Е		E		
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)					_		
,	Musculo-skeletal (Convent.)							
:	Musculo-skeletal (Superficial)	:						
	Intravascular							
	Intra-luminal							
	Cardiac Adult				•			
	Cardiac Adult, TEE							
Cardiac	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)				1			
Peripheral	Peripheral Vascular							
Vessel	Other: Gynecological							

E=added under Appendix E

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

Other:

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Prescription Use (Per 21 CFR 801.109)

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Office of in vitro Diagnostics and Radiological Health

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System: <u>Prosound F75</u> Transducer: ASU-1010

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application					of Operation		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P		P	Note 1	
·	Abdominal	Ρ.	P	P		Р	Note I	
	Intra-operative (Specify)							
	Intra-operative (Neuro)						<u> </u>	
	Laparoscopic							
	Pediatric							
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic							
	Adult Cephalic						<u></u>	
	Trans-rectal						·	
	Trans-vaginal		-					
	Trans-urethral							
	TEE (non-Cardiac)							ļ. <u> </u>
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular .							
	Intra-luminal							
	Cardiac Adult							
[	Cardiac Adult, TEE							
Cardiac	Cardiac- Neonatal							
Ì	Cardiac Pediatric, TEE							
Ì	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral	Peripheral Vascular							
Vessel	Other: Gynecological	P	· P	P		. P	Note 1	

P= previously cleared by FDA- (K110207)

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Office of In Vitro Diagnostics and Radiological Health

510(K) K123828

System: <u>Prosound F75</u> Transducer: ASU-1012

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application					of Operation		
General	Specific	В	M	PWD	CWD	Color	Combined	Other
(Track 1 Only)	(Tracks 1 & 3)					Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic							
	Fetal	Е	Е	E				
	Abdominal							
	Intra-operative (Specify)							-
·	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic					<u> </u>		
[	Adult Cephalic					<u> </u>		
	Trans-rectal					<u> </u>		,
	Trans-vaginal	Е	Е	Е				
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal							
Į.	(Superficial)							
	Intravascular				<u> </u>			
	Intra-luminal							
	Cardiac Adult							
I	Cardiac Adult, TEE							
Cardiac	Cardiac- Neonatal			<u> </u>				-
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral	Peripheral Vascular							
Vessei	Other: Gynecological	Е	E	E				

E=added under Appendix E

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

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System: Prosound F75 Transducer: ASU-1013

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)	
Ophthalmic	Ophthalmic				. <u> </u>				
	Fetal							ļ <u> </u>	
	Abdominal					<u> </u>			
	Intra-operative (Specify)		<u></u>	_					
	Intra-operative (Neuro)		ļ					<u> </u>	
	Laparoscopic							ļ	
•	Pediatric							<u> </u>	
Fetal Imaging	Small Organ (Specify)	E	E	E					
& Other	Neonatal Cephalic					<u> </u>	_		
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	TEE (non-Cardiac)						_		
	Musculo-skeletal (Convent.)				<u> </u>				
	Musculo-skeletal (Superficial)								
	Intravascular								
	Intra-luminal			•	<u> </u>			<u> </u>	
	Cardiac Adult							<u> </u>	
	Cardiac Adult, TEE								
Cardiac	Cardiac- Neonatal				<u> </u>			ļ	
	Cardiac Pediatric, TEE		_		<u> </u>				
	Intravascular (Cardiac)		<u> </u>					<u> </u>	
	Other (Specify)								
Peripheral	Peripheral Vascular							ļ	
Vessel	Other: Gynecological								

E=added under Appendix E

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD Other:

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Prescription Use (Per 21 CFR 801.109)

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System: Prosound F75 Transducer: UST-2265-2

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application			<u> </u>		of Operation		
General	Specific	В	M	PWD	CWD	Color	Combined	. Other
(Track 1 Only)	(Tracks 1 & 3)					Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal		<u> </u>					
	Intra-operative (Specify)							ļ
	Intra-operative (Neuro)		<u> </u>					
	Laparoscopic .		<u> </u>					
	Pediatric							
Fetal Imaging	Small Organ (Specify)					<u> </u>		ļ
& Other	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)					ļ		
	Musculo-skeletal							
	(Superficial)			ļ		ļ		
	Intravascular							
	Intra-luminal							
	Cardiac Adult				P			
	Cardiac Adult, TEE							
Cardiac	Cardiac- Neonatal							
	Cardiac Pediatric, TEE			<u> </u>				
	Intravascular (Cardiac)		<u> </u>					
	Other (Specify)				]			1
Peripheral	Peripheral Vascular							
Vessel	Other :Gynecological							•

N = new indication; P= previously cleared by FDA- (K110207)

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)
Sean M. Boyd -S

(Division Sign Off)

Division of Hadiological Health

System: Prosound F75 Transducer: UST-2266-5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)		
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal									
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic						<u> </u>			
	Pediatric							<u> </u>		
Fetal Imaging	Small Organ (Specify)					<u> </u>		<u> </u>		
& Other	Neonatal Cephalic		]				<u> </u>			
ſ	Adult Cephalic					_				
Γ	·Trans-rectal									
	Trans-vaginal									
Γ	Trans-urethral									
	TEE (non-Cardiac)						_l			
	Musculo-skeletal (Convent.)									
Γ	Musculo-skeletal (Superficial)									
	Intravascular							<u> </u>		
	Intra-luminal									
	Cardiac Adult				P					
	Cardiac Adult, TEE									
Cardiac	Cardiac- Neonatal									
	Cardiac Pediatric, TEE									
	Intravascular (Cardiac)									
	Other (Specify)							<u> </u>		
Peripheral	Peripheral Vascular				P					
Vessel	Other :Gynecological									

P= previously cleared by FDA- (K110207)

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)
Sean M. Boyd -S

(Division Sign Off)

Division of Radiological Health

System: <u>Prosound F75</u> Transducer: UST-5293-5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

				Mode	of Operation			
General	Clinical Application Specific	В	M	PWD	CWD	Color	Combined	Other
(Track 1 Only)	(Tracks 1 & 3)					Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic					<u> </u>		
	Fetal					<u> </u>		
	Abdominal					٠.		
	Intra-operative (Specify)		1					
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic		I					
ĺ	Adult Cephalic							
	Trans-rectal .						<u> </u>	
	Trans-vaginal			1				
	Trans-urethral							
	TEE (non-Cardiac)		_					
	Musculo-skeletal (Convent.)						ļ. <u></u>	
	Musculo-skeletal						1	
	(Superficial)		<u> </u>				<u> </u>	
	Intravascular		1				ļ	
	Intra-luminal							
	Cardiac Adult	P	P	P	P	P	Note 1, 2	
· [	Cardiac Adult, TEE	N	N	N	N	N N	Note 1, 2	
Cardiac	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							<u> </u>
	Intravascular (Cardiac)		1					<u> </u>
	Other (Specify)		<u> </u>				1	
Peripheral	Peripheral Vascular							
Vessel	Other: Gynecological						1	

N = new indication; P = previously cleared by FDA -(K110207)

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

51U(K) K123828

System: Prosound F75 Transducer: UST-5411

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application				Mode	of Operation		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic `							
	Fetal							
	Abdominal							
	Intra-operative (Specify)							<u> </u>
	Intra-operative (Neuro)							<u> </u>
	Laparoscopic							
	Pediatric							
Fetal Imaging	Small Organ (Specify)*	P	P	P		P	Note 1	
& Other	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
[	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
<u> </u>	Musculo-skeletal (Convent.)	P	P	P		Р	Note 1	
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
	Cardiac Adult							
	Cardiac Adult, TEE					•		
Cardiac	Cardiac- Neonatal					,		
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)				- "			
	Other (Specify)							
Peripheral	Peripheral Vascular	P	P	P		P	Note 1	
Vessel	Other :Gynecological							

N = new indication; P= previously cleared by FDA- (K110207)

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

\*Applications: Small Parts: (breast, testes, & thyroid...)

Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)
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(Division Sign Off)

Division of Radiological Health

System: <u>Prosound F75</u> Transducer: UST-5415

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application				Mode	of Operation		
General	Specific	В	M	PWD	CWD	Color	Combined	Other
(Track 1 Only)	(Tracks 1 & 3)					Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic							ļ
	Fetal				ļ			<u> </u>
	Abdominal				<u> </u>	<u> </u>		
	Intra-operative (Specify)				ļ	<u> </u>		ļ
	Intra-operative (Neuro)				<b>_</b>	<u> </u>		
	Laparoscopic					.		<u> </u>
	Pediatric				1	<u> </u> -		
Fetal Imaging	Small Organ (Specify)*	.Р	P	P	ļ	P	Note 1	
& Other	Neonatal Cephalic							
	Adult Cephalic							ļ
	Trans-rectal							<u> </u>
	Trans-vaginal							<u> </u>
•	Trans-urethral							
	TEE (non-Cardiac)				<u> </u>			<u> </u>
,	Musculo-skeletal (Convent.)	P	P	P		P	Note 1	
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
	Cardiac Adult							
	Cardiac Adult, TEE	·						
Cardiac	Cardiac- Neonatal							
	Cardiac Pediatric, TEE		<u> </u>					
	Intravascular (Cardiac)							<u> </u>
	Other (Specify)							-
Peripheral	Peripheral Vascular	P	P	P		P	Note 1	
Vessel	Other: Gynecological						1	

P= previously cleared by FDA- (K110207)

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

\*Applications: Small Parts - (breast, testes, & thyroid...), Intra-operative - (liver, pancreas, gall bladder...)

Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)
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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510pg K123828

System: Prosound F75 Transducer: UST-5417

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application			•		of Operation		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic		_			Боррісі	(opecity)	(Speeding)
Ophinannie	Fetal							
	Abdominal			· · ·		_		<u> </u>
	Intra-operative (Specify)							
	Intra-operative (Neuro)		1					
<b>!</b>	Laparoscopic		1.	i				
	Pediatric							
Fetal Imaging	Small Organ (Specify)*	Е	Е	Е				
& Other	Neonatal Cephalic							<u> </u>
[	Adult Cephalic						_	<u> </u>
1	Trans-rectal							
	Trans-vaginal					<u></u>		<u> </u>
	Trans-urethral							
	TEE (non-Cardiac)						•	<u> </u>
	Musculo-skeletal (Convent.)							·
	Musculo-skeletal (Superficial)			•				
ſ	Intravascular							
	Intra-luminal		_					
	Cardiac Adult							
	Cardiac Adult, TEE	· ·						
Cardiac	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							<u> </u>
Ĺ	Intravascular (Cardiac)		<u> </u>	ļ				-
	Other (Specify)							<u> </u>
Peripheral	Peripheral Vascular	Е	E	E				
Vessel	Other: Gynecological						<u> </u>	

E=added under Appendix E

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Radiological Health

<sup>\*</sup>Applications: Small Parts - (breast, testes, & thyroid...), Intra-operative - (liver, pancreas, gall bladder...)

System: Prosound F75
Transducer: UST-5419

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application					of Operation		
General	Specific	В	M	PWD	CWD	Color	Combined	Other
(Track 1 Only)	(Tracks 1 & 3)					Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal	Е	E	E				<u> </u>
	Intra-operative (Specify)							ļ
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic			]				
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal							
	(Superficial)			1				
	Intravascular							
	Intra-luminal							
	Cardiac Adult							
	Cardiac Adult, TEE		1					
Cardiac	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)		_					
	Other (Specify)							
Peripheral	Peripheral Vascular	E	E	E				
Vessel	Other: Gynecological							

E=added under Appendix E

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Radiological Health.

Office of In Vitro Diagnostics and Radiological Health

510(k) /K/23828

System: Prosound F75 Transducer: UST-5713T

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human	body as follows:
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	Clinical Application			•	Mode	of Operation		
General	Specific '	В	M	PWD	CWD	Color	Combined	Other
(Track 1 Only)	(Tracks 1 & 3) Ophthalmic					Doppler	(Specify)	(Specify)
Ophthalmic						<u> </u>	<del>-</del>	
	Fetal		<del> </del>	<del> </del>				<del> </del>
-	Abdominal	Е						
	Intra-operative (Specify)	Е	E	E			-	<del></del>
}	Intra-operative (Neuro)						<del> </del>	
	Laparoscopic						<del> </del>	
	Pediatric			· · · · · · · · · · · · · · · · · · ·			<del> </del>	
Fetal Imaging	Small Organ (Specify)							· · · · · · · · · · · · · · · · · · ·
& Other	Neonatal Cephalic						ļ	
ļ.	Adult Cephalic							
Į.	Trans-rectal							
	Trans-vaginal							ļ
	Trans-urethral							
Ĺ	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							_
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal		•					
	Cardiac Adult							
	Cardiac Adult, TEE							
Cardiac	Cardiac- Neonatal	•						
	Cardiac Pediatric, TEE				·			
ſ	Intravascular (Cardiac)							
Ī	Other (Specify)				<del>.</del>			
Peripheral	Peripheral Vascular							
Vessel	Other: Gynecological							

E=added under Appendix E

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)
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(Division Sign Off)

Division of Radiological Health

System: <u>Prosound F75</u> Transducer: UST-9115-5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application					of Operation		
General	Specific	В	M	PWD	CWD	Color	Combined	Other
(Track 1 Only)	(Tracks 1 & 3)		ļ. <u>.</u>			Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic							
	Fetal							<u> </u>
	Abdominal	E	E	E				
	Intra-operative (Specify)						,	<u> </u>
	Intra-operative (Neuro)							ļ
	Laparoscopic							
	Pediatric							
Fetal Imaging	Small Organ (Specify)			<u> </u>				<u> </u>
& Other	Neonatal Cephalic							<u> </u>
	Adult Cephalic		٠					
	Trans-rectal							
Ī	Trans-vaginal							
	Trans-urethral			<u> </u>	<u></u>			
	TEE (non-Cardiac)		<u> </u>	ļ. <u></u>	<u> </u>			
	Musculo-skeletal (Convent.)			ļ <u></u>				
	Musculo-skeletal				1			
	(Superficial)							
	Intravascular		<u> </u>				<u> </u>	
	Intra-luminal		_					
	Cardiac Adult	<u> </u>						
	Cardiac Adult, TEE			ļ.,				
Cardiac	Cardiac- Neonatal				ļ			<u> </u>
	Cardiac Pediatric, TEE	<u> </u>						
	Intravascular (Cardiac)							
:	Other (Specify)					<u> </u>		
Peripheral	Peripheral Vascular							<u> </u>
Vessel	Other: Gynecological	Е	E	E	<u> </u>	1		1

E=added under Appendix E

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)
Sean M. Boyd -S

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123828

System: Prosound F75 Transducer: UST-9118

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

(	Clinical Application				Mode	of Operation		
General	Specific	В	M	PWD	CWD	Color	Combined	Other
(Track 1 Only)	(Tracks 1 & 3)					Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P		P	Note 1	
	Abdominal		1		<u> </u>			<del> </del>
	Intra-operative (Specify)							ļ
	Intra-operative (Neuro)	<u> </u>				ļ <u>.</u>		
	Laparoscopic	<u> </u>						
	Pediatric	<u> </u>				<u> </u>		
Fetal Imaging	Small Organ (Specify)		ļ					
& Other	Neonatal Cephalic		ļ			<u> </u>		
	Adult Cephalic				ļ		<u> </u>	<del>                                      </del>
	Trans-rectal					ļ		<u> </u>
	Trans-vaginal	P	P	P		P	Note 1	
	Trans-urethral							<u> </u>
	TEE (non-Cardiac)		<u> </u>					
	Musculo-skeletal (Convent.)				<u>.                                    </u>			<del></del>
	Musculo-skeletal (Superficial)							
_ , _ [	Intravascular							<del> </del>
Г	Intra-luminal		<u> </u>					
	Cardiac Adult					<u> </u>		ļ. <u></u>
	Cardiac Adult, TEE				<u> </u>			
Cardiac	Cardiac- Neonatal							<del> </del>
	Cardiac Pediatric, TEE					<u> </u>		ļ
	Intravascular (Cardiac)				<u> </u>			
	Other (Specify)							
Peripheral	Peripheral Vascular						<u> </u>	<u> </u>
Vessel	Other: Gynecological	P	P	P		P	Note 1	

P= previously cleared by FDA- (K110207)

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Sean M. Boyd -S

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Division of Radiological Health

System: <u>Prosound F75</u> Transducer: UST-9120

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application			,	Mode	of Operation		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
+	Fetal							
	Abdominal							
	Intra-operative (Specify)	Е	Е	E				
	Intra-operative (Neuro)					-		
	Laparoscopic			<u>.</u>				
	Pediatric							
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic	Е	Е	Е				
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)			,				
	Musculo-skeletal							
·  -	(Superficial) Intravascular							
	Intra-luminal							1
	Cardiac Adult		<del> </del>	<u> </u>			<u> </u>	<b> </b>
-	Cardiac Adult, TEE	<del></del>		<del>       </del>		•		<del> </del>
Cardiac	Cardiac-Neonatal						1	<u> </u>
Cardiac	Cardiac Pediatric, TEE							
F	Intravascular (Cardiac)		1					<del> </del>
<u> </u> -	Other (Specify)		<del> </del>	<del>  </del>				
Peripheral	Peripheral Vascular			+		······································	<del> </del>	
Vessel	Other: Gynecological						<del> </del>	1
7 00001	Omer: Oynecological							1

E=added under Appendix E

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K/23828

System: <u>Prosound F75</u> Transducer: UST-9130

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application				Mode	of Operation		
General	Specific	В	M	PWD	CWD	Color	Combined	Other
(Track 1 Only)	(Tracks 1 & 3)		<u> </u>			Doppler -	(Specify)	(Specify)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P	_	P	Note 1	
	Abdominal	P	P	P		<u> P</u>	Note 1	
	Intra-operative (Specify)							<u> </u>
	Intra-operative (Neuro)							
	Laparoscopic					<u> </u>		
	Pediatric					<u> </u>		
Fetal Imaging	Small Organ (Specify)			<u> </u>				
& Other	Neonatal Cephalic		<u> </u>					
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal					<u> </u>		
	Trans-urethral							
	TEE (non-Cardiac)				_			
	Musculo-skeletal (Convent.)					<u>.</u>		
	Musculo-skeletal							
	(Superficial)			ļ		ļ·		
	Intravascular			<u> </u>	<u> </u>			<u> </u>
	Intra-luminal		ļ	<u> </u>				
	Cardiac Adult					<u> </u>		
L	Cardiac Adult, TEE		_					
Cardiac	Cardiac- Neonatal						_	,
	Cardiac Pediatric, TEE	<u> </u>			ļ			
	Intravascular (Cardiac)							
	Other (Specify)		<u> </u>					
Peripheral	Peripheral Vascular							
Vessel	Other: Gynecological	P	P	P		P	Note 1	

N = new indication; P= previously cleared by FDA- (K110207)

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Sean M. Boyd -S

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510M K123828

System: Prosound F75 Transducer: UST-9132 I & T

Intended Use: D	iagnostic ultrasound	imaging or fluid	flow analysis of	f the human bod	y as follows:

	Clinical Application				Mode	of Operation		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic	·						
	Fetal					<u></u>		
	Abdominal							
	Intra-operative (Specify)	E	E	E				<u> </u>
L	Intra-operative (Neuro)			ļ <u></u>		<u>.</u>	<u> </u>	
	Laparoscopic							
	Pediatric							
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic	***						ļ
	Adult Cephalic							
	Trans-rectal						<u> </u>	
	Trans-vaginal					<u> </u>		<del> </del>
	Trans-urethral							
	TEE (non-Cardiac)		<u> </u>					
	Musculo-skeletal (Convent.)							<u> </u>
	Musculo-skeletal (Superficial)							
	Intravascular		<u> </u>	<u> </u>				·
ſ	Intra-luminal							
	Cardiac Adult							<del> </del>
	Cardiac Adult, TEE				ļ <u></u>			
Cardiac	Cardiac- Neonatal				<u>  ·                                     </u>			<u> </u>
. [	Cardiac Pediatric, TEE							<u> </u>
	Intravascular (Cardiac)					ļ		
	Other (Specify)			<u> </u>				
Peripheral	Peripheral Vascular				<u> </u>			
Vessel	Other: Gynecological							<u> </u>

E=added under Appendix E

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Sean M. Boyd -S

(Division Sign Off)

Division of Radiological Health

System: <u>Prosound F75</u> Transducer: UST-9133

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

<u>-</u>	Clinical Application					of Operation		
General	Specific	В	M	PWD	CWD	Color	Combined	Other
(Track 1 Only)	(Tracks 1 & 3)					Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic				-			<u> </u>
	Fetal		<u> </u>				<u> </u>	
	Abdominal							
	Intra-operative (Specify)*	P	P	P		P	Note 1	
	Intra-operative (Neuro)							
	Laparoscopic							<u> </u>
	Pediatric							ļ
Fetal Imaging	Small Organ (Specify)		1					
& Other	Neonatal Cephalic	P	P	P		P	Note 1	
	Adult Cephalic							
	Trans-rectal				_			
	Trans-vaginal							<u> </u>
	Trans-urethral		٠				·	
	TEE (non-Cardiac)			_				
	Musculo-skeletal (Convent.)			ļ .				
	Musculo-skeletal		1		į	1.		
	(Superficial)							
	Intravascular							
	Intra-luminal							<u> </u>
	Cardiac Adult					ļ		
	Cardiac Adult, TEE		<u> </u>	-				<del> </del>
Cardiac	Cardiac- Neonatal						<u> </u>	<u> </u>
	Cardiac Pediatric, TEE		<u> </u>			<del> </del>		
	Intravascular (Cardiac)			<del> </del>		<u> </u>		<u> </u>
	Other (Specify)						` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` `	
Peripheral	Peripheral Vascular					ļ		
Vessel	Other: Gynecological		1	<u> </u>		1	,	

P= Previously cleared by FDA- (K110207)

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

\*Applications: Intra-operative - (liver, pancreas, gall bladder...)

Other:

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) 14/03808

System: <u>Prosound F75</u> Transducer: UST-9135P

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application				Mode	of Operation		
General	Specific	В	M	PWD	CWD	Color	Combined	Other
(Track 1 Only)	(Tracks 1 & 3)					Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic				<u> </u>			<u> </u>
	Fetal							
	Abdominal	E	Е	E				ļ
	Intra-operative (Specify).							<b>_</b>
	Intra-operative (Neuro)		_					
	Laparoscopic							
	Pediatric				·			
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal					_		
Í	Trans-urethral					ľ		
Ï	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)					<u></u>		
	Musculo-skeletal							
	(Superficial)							ļ. —
	Intravascular							
	lntra-luminal							
	Cardiac Adult				_	ļ		
	Cardiac Adult, TEE							
Cardiac	Cardiac- Neonatal							ļ,
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)			<u> </u>				
Peripheral	Peripheral Vascular							
Vessel	Other: Gynecological							

E=added under Appendix E

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Sean M. Boyd -S

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510kg K123828

System: <u>Prosound F75</u> Transducer: UST-9146 I&T

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application					of Operation		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
	Fetal							<u></u>
	Abdominal			<u> </u>				
Γ	Intra-operative (Specify)	Р _	P	P	P		Note I	
Γ	Intra-operative (Neuro)			<u> </u>				
	Laparoscopic			<u> </u>				
	Pediatric							
Fetal Imaging	Small Organ (Specify)			1				
& Other	Neonatal Cephalic		<u> </u>					
	Adult Cephalic		<u> </u>					
	Trans-rectal		<u> </u>				<u> </u>	
	Trans-vaginal							<u> </u>
	Trans-urethral							<u> </u>
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
, ,	Intravascular							
	Intra-luminal							
	Cardiac Adult							
	Cardiac Adult, TEE							<u> </u>
Cardiac	Cardiac- Neonatal				ļ			<del> </del>
	Cardiac Pediatric, TEE		<u>                                     </u>	ļ				
	Intravascular (Cardiac)		·	<u> </u>			Note 1	<u> </u>
	Other (Specify)		`					ļ
Peripheral	Peripheral Vascular							ļ
Vessel	Other: Gynecological							

P= previously cleared by FDA- (K110207)

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123828

System: <u>Prosound F75</u> Transducer: UST-9147

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application				Mode	of Operation	-	
General	Specific	В	M	PWD	CWD	Color	Combined	Other
(Track 1 Only)	(Tracks 1 & 3)		<u> </u>			Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic	<u> </u>	1					
	Fetal	P	P	P		P	Note I	
	Abdominal	P	P	P		P	Note I	
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic		1					<u> </u>
·	Pediatric							
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
. [	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal				,			
	Cardiac Adult		i					
ſ	Cardiac Adult, TEE							
Cardiac	Cardiac- Neonatal							
Ī	Cardiac Pediatric, TEE							
ſ	Intravascular (Cardiac).							
	Other (Specify)							
Peripheral	Peripheral Vascular							
Vessel	. Other: Gynecological	P	Р	P		P	Note 1	

P= previously cleared by FDA- (K110207)

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)
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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) 19123828

System: <u>Prosound F75</u> Transducer: UST-52105

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

inical Application Specific	В	Mode of Operation					
(Tanaka 1 & 3)	D	M <sub>.</sub>	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
(Tracks 1 & 3)		<del>                                     </del>				(CPSSS)	
			-				
		+	<del> </del>			<del>                                     </del>	
			<del> </del>		-		
		<del>                                     </del>	<del> </del>				<del>                                     </del>
			1			T	<u> </u>
1		<del>                                     </del>		<u> </u>			†
		+	<del> </del>				
				,		<del> </del>	
	-		-				<u> </u>
					,	<u> </u>	
		<b>-</b>					<u> </u>
		-					
	<u>-</u> _	<del>-</del>	<del> </del>	· · · · · · · · · · · · · · · · · · ·	-	<del> </del>	
		+			-	<del></del>	<u> </u>
		+					
			<b></b>				
			1				T. ""
	P	Р	P	P	P	Note 1 & 2	
·		1	· · · · · · · · · · · · · · · · · · ·				
		·					
		1		·			
				1		(Specify)	
				, ,		Note 1 & 2	
					1		
				<u> </u>			
	Ophthalmic Fetal Abdominal Intra-operative (Specify) Intra-operative (Neuro) Laparoscopic Pediatric Small Organ (Specify) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral TEE (non-Cardiac) Musculo-skeletal (Convent.) Musculo-skeletal (Superficial) Intravascular Intra-luminal Cardiac Adult Cardiac Adult, TEE Cardiac- Neonatal Cardiac Pediatric, TEE Intravascular (Cardiac) Other (Specify) Peripheral Vascular Other: Gynecological	Fetal Abdominal Intra-operative (Specify) Intra-operative (Neuro) Laparoscopic Pediatric Small Organ (Specify) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral TEE (non-Cardiac) Musculo-skeletal (Convent.) Musculo-skeletal (Superficial) Intra-luminal Cardiac Adult Cardiac Adult, TEE Cardiac- Neonatal Cardiac Pediatric, TEE Intravascular Other (Specify) Peripheral Vascular Other: Gynecological	Fetal Abdominal Intra-operative (Specify) Intra-operative (Neuro) Laparoscopic Pediatric Small Organ (Specify) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral TEE (non-Cardiac) Musculo-skeletal (Convent.) Musculo-skeletal (Superficial) Intra-luminal Cardiac Adult Cardiac Adult, TEE Cardiac Neonatal Cardiac Pediatric, TEE Intravascular Other (Specify) Peripheral Vascular Other: Gynecological	Fetal Abdominal Intra-operative (Specify) Intra-operative (Neuro) Laparoscopic Pediatric Small Organ (Specify) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral TEE (non-Cardiac) Musculo-skeletal (Convent.) Musculo-skeletal (Superficial) Intra-luminal Cardiac Adult Cardiac Adult, TEE Cardiac-Neonatal Cardiac Pediatric, TEE Intravascular Other (Specify) Peripheral Vascular Other: Gynecological	Ophthalmic Fetal Abdominal Intra-operative (Specify) Intra-operative (Neuro) Laparoscopic Pediatric Small Organ (Specify) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral TEE (non-Cardiac) Musculo-skeletal (Convent.) Musculo-skeletal (Superficial) Intravascular Intra-luminal Cardiac Adult Cardiac Adult, TEE Cardiac- Neonatal Cardiac Pediatric, TEE Intravascular (Cardiac) Other (Specify) Peripheral Vascular Other: Gynecological	Ophthalmic Fetal Abdominal Intra-operative (Specify) Intra-operative (Neuro) Laparoscopic Pediatric Small Organ (Specify) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral TEE (non-Cardiac) Musculo-skeletal (Convent.) Musculo-skeletal (Superficial) Intravascular Intra-luminal Cardiac Adult P P P P P Cardiac Adult, TEE Cardiac- Neonatal Cardiac Pediatric, TEE Intravascular (Cardiac) Other (Specify) Peripheral Vascular Other: Gynecological	Ophthalmic         Fetal           Abdominal         Intra-operative (Specify)           Intra-operative (Neuro)         Intra-operative (Neuro)           Laparoscopic         Pediatric           Small Organ (Specify)         Small Organ (Specify)           Neonatal Cephalic         Adult Cephalic           Trans-rectal         Trans-vaginal           Trans-vaginal         Trans-urethral           TEE (non-Cardiac)         Musculo-skeletal (Convent.)           Musculo-skeletal (Convent.)         Musculo-skeletal (Superficial)           Intra-luminal         Intra-luminal           Cardiac Adult         P         P         P         P         P         P         Note 1 & 2           Cardiac Pediatric, TEE         Intravascular (Cardiac)         Intravascular (Cardiac)         Other (Specify)         Intravascular (Cardiac)         Other: Gynecological

P= previously cleared by FDA- (K110207)

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)
Sean M. Boyd -S

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) 19123828

System: <u>Prosound F75</u> Transducer: UST-52110S

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application				Mode	of Operation		•
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic		<del> </del>	<u> </u>	-	Боррісі	(Specify)	(Бреспу)
·	Fetal			+				
	Abdominal			1.				
	Intra-operative (Specify)							1
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric		1 "					
Fetal Imaging	Small Organ (Specify)							
& Other	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	·		,				
	Trans-urethral							
	TEE (non-Cardiac)			<u> </u>	<u>.</u>			
Į.	Musculo-skeletal (Convent.)							ļ
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							-
	Cardiac Adult						'	
	Cardiac Adult, TEE							
Cardiac	Cardiac- Neonatal	N	N	N				
	Cardiac Pediatric, TEE		ļ <u> </u>					
	Intravascular (Cardiac)							,
	Other (Specify)							
Peripheral	Peripheral Vascular		ļ	ļ				
Vessel	Other: Gynecological							<u> </u>

N = new indication

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)
Sean M. Boyd -S

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510M K123828

System: Prosound F75 Transducer: UST-52120S

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	ended Use: Diagnostic ultrasound Clinical Application			<u> </u>	Mode	of Operation		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Оримини	Fetal						<del></del>	<u> </u>
<u> </u>	Abdominal				ļ			<del> </del>
-	Intra-operative (Specify)						<del></del>	<del>                                     </del>
·	Intra-operative (Neuro)						<u></u>	<del> </del>
	Laparoscopic					ļ	<del>-  </del>	<del> </del>
	Pediatric				<u> </u>			<del> </del>
Fetal Imaging	Small Organ (Specify)		<u> </u>	<u> </u>		<del> </del>		<del> </del>
& Other	Neonatal Cephalic			<u> </u>		ļ	<del></del>	<del>├</del>
Ţ.	Adult Cephalic					<u> </u>	_	<del> </del> -
<u> </u>	Trans-rectal					ļ		<del> </del>
Ī	Trans-vaginal					<u> </u>		<del> </del>
Γ	Trans-urethral				ļ <u>.</u>	<del> </del>		<del> </del>
	TEE (non-Cardiac)	<u></u>			<del> </del>	<del> </del>		<del> </del>
ľ	Musculo-skeletal (Convent.)				ļ	<del> </del>		+
	Musculo-skeletal (Superficial)			ļ				
[	Intravascular				<del> </del>		<del></del>	<del> </del>
ľ	Intra-luminal					<del>-</del>		+
	Cardiac Adult				<del> </del>	<del> </del>		<del></del> -
Ī	Cardiac Adult, TEE				<del> </del>		Note 1 & 2	<del> </del>
Cardiac	Cardiac- Neonatal	E	E	E	E	E	Note 1 & 2	+
	Cardiac Pediatric	E	E	E	E	E	Note I & 2	<del></del>
	Intravascular (Cardiac)	ļ			<del> </del>	<del> </del>		
	Other (Specify)							+
Peripheral	Peripheral Vascular	<u> </u>			<del> </del>			<del></del>
Vessel	Other: Gynecological	<u> </u>						

N = new indication

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)
Seams Msighory d -S

Division of Radiological Health

whose or In Vitro Diagnostics and Radiological Health

System: Prosound F75 Transducer: UST-52114P

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application					of Operation		
General	Specific	В	M	PWD	CWD	Color	Combined	Other
(Track 1 Only)	(Tracks 1 & 3)					Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic			'				
	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative	N	N	N		}		
,	(Neurosurgery)							
	Laparoscopic			<u> </u>				
Fetal Imaging	Pediatric							<u> </u>
& Other	Small Organ (Specify)							
	Neonatal Cephalic		ļ				***************************************	
1	Adult Cephalic							
į	Trans-rectal							
	Trans-vaginal							<u> </u>
	Trans-urethral							
	TEE (non-Cardiac)				,			
. [	Musculo-skeletal (Convent.)							
	Musculo-skeletal							
•	(Superficial)							
	Intravascular							
	Intra-luminal							
<u> </u>	Cardiac Adult							
[	Cardiac Adult, TEE					:		
Cardiac	Cardiac- Neonatal							
1	Cardiac Pediatric, TEE		ļ	<u>                                     </u>				
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral	Peripheral Vascular							
Vessel	Other: Gynecological							

N = new indication

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)
Sean M. Boyd -S

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Division of Radiological Health

System: Prosound F75 Transducer: UST-52119S

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	-	·		Mode	of Operation		
General	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
(Track 1 Only) Ophthalmic	Ophthalmic					Ворр.с.	(CF)	
Ophinamic	Fetal				_			
	Abdominal		_			<u> </u>		
	Intra-operative (Specify)					· · ·		
	Intra-operative (Neuro)							
	Laparoscopic			1				
	Pediatric					-		
Fetal Imaging	Small Organ (Specify)	<del></del>						
& Other	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							<u> </u>
	Trans-urethral							ļ <u> </u>
	TEE (non-Cardiac)					<u> </u>		<u> </u>
	Musculo-skeletal (Convent.)							ļ
	Musculo-skeletal (Superficial)						·	
	Intravascular							
	Intra-luminal							
	Cardiac Adult							
	Cardiac Adult, TEE							
Cardiac	Cardiac- Neonatal							
	Cardiac Pediatric, TEE	N	N	N	N	<u> </u>	Note 1, 2, 3	
	Intravascular (Cardiac)			_		ļ		
	Other (Specify)				<u> </u>			
Peripheral	Peripheral Vascular		1	ļ			·	
Vessel	Other: Gynecological		1		<u>.                                    </u>		<u> </u>	<u> </u>

N = new indication

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

Note 3: Cardiac, Pediatric cleared by FDA - (K110287)

Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)
Sean M. Boyd -S

(Division Sign Off)

Division of Radiological Health

System: Prosound F75 Transducer: UST-52121S

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application				Mode	of Operation		<del>, </del>
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
	Fetal	<u>.</u>					ļ <u> </u>	
	Abdominal						<u> </u>	
	Intra-operative (Specify)							<u> </u>
. [	Intra-operative (Neurosurgery))	. <u> </u>						
ŗ	Laparoscopic						<u> </u>	
Fetal Imaging	Pediatric	·						
& Other	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal		ļ			<u> </u>		
	Trans-vaginal							<del> </del>
	Trans-urethral					ļ		
Ε	TEE (non-Cardiac)			<u> </u>				
	Musculo-skeletal (Convent.)							<del> </del>
	Musculo-skeletal (Superficial)							
Γ	Intravascular							<del>-</del>
Γ	Intra-luminal					ļ	<u> </u>	
	Cardiac Adult			<u> </u>				
	Cardiac Adult, TEE		ļ					<del> </del>
Cardiac	Cardiac- Neonatal		<u> </u>	ļ <u>-</u>		<del> </del>		<del> </del>
	Cardiac Pediatric, TEE	N	N_	N	N	N	Note 1,2, 3	<del> </del>
	Intravascular (Cardiac)		ļ		<u> </u>		Combined (Specify)  Note 1,2, 3	<del> </del>
	Other (Specify)				ļ			<del>                                      </del>
Peripheral	Peripheral Vascular		<u> </u>	_		<u> </u>	<del> </del>	
Vessel	Other: Gynecological					<u> </u>		<u> </u>

N = new indication

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD

Note 3: Cardiac, Pediatric cleared by FDA - (K110287)

Other:

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Sean M. Boyd -S

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Division of Radiological Health

System: <u>Prosound F75</u> Transducer: UST-52124

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application					of Operation		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmi	Ophthalmic							
C								
	Fetal							
· .	Abdominal							
L	Intra-operative (Specify)	,						
L	Intra-operative (Neuro)					"		
L	Laparoscopic							
L	Pediatric							
Fetal Imaging	Small Organ (Specify)		1.					
& Other	Neonatal Cephalic	P	P	P	P	Р	Note 1, 2	
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral						-	
	TEE (non-Cardiac)							
<b>_</b>	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
<u> </u>	Intravascular		1			- <u></u>	<del></del>	
· -	Intra-luminal						<u>.</u>	
	Cardiac Adult		<u> </u>			<u></u>		
<u> </u>	Cardiac Adult, TEE		<u> </u>			<u>-</u>		
Cardiac	Cardiac- Neonatal	P	P	P	P	P	Note 1, 2	
	Cardiac-Pediatric	N	N	N	N	N N	Note 1, 2	
	Cardiac Pediatric, TEE		•			14	1.010 1, 2	
<u> </u>	Intravascular (Cardiac)			1			,	
<u> </u> -	Other (Specify)						-	<del></del>
Peripheral	Peripheral Vascular			<del>                                     </del>		·	<del>                                     </del>	
Vessel	Other: Gynecological			<del>  .  </del>			+	
NI	2= previously cleared by FDA (K110		<u> </u>				<u> </u>	

N = new indication; P= previously cleared by FDA- (K110207)

Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Sean M. Boyd -S

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(K) K123828

System: Prosound F75 Transducer: GF-UE160 AL5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation								
General (Track 1 Only)	Clinical Application Specific (Tracks 1 & 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)	
Ophthalmic	Ophthalmic		]						
	Fetal								
ľ	Abdominal	P	P	P		P	Note 1		
	Intra-operative (Specify)	P	P	P		P	Note 1		
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
[	Small Organ (Specify)	<u></u>						1	
Fetal Imaging	Neonatal Cephalic							J	
& Other	Adult Cephalic	·	<u> </u>	<u> </u>					
	Trans-rectal			<u> </u>					
	Trans-vaginal		<u>.</u>						
	Trans-urethral			ļ					
	TEE (non-Cardiac)	P	P	P		P	Note I	<del> </del> -	
Į.	Musculo-skeletal (Convent.)		ļ <u>.</u>	<del> </del>		ļ		<del> </del>	
	Musculo-skeletal					1			
<b> </b>	(Superficial)		<del> </del>			<u> </u>		-	
	Intravascular		<u> </u>				<del>- </del> -		
	Intra-luminal		P	P		P	Note 1	-	
	Others (Specify) Note 2	P	P	P	<u> </u>	<u></u>	Note 1	<del> </del>	
	Cardiac Adult		<del> </del>	<del> </del>		<u> </u>			
Cardiac	Cardiac Adult, TEE		<del>                                     </del>	ļ			<u> </u>	<del>-</del>	
	Cardiac- Neonatal					<u> </u>		<u> </u>	
	Cardiac Pediatric, TEE							ļ	
	Intravascular (Cardiac)		1						
	Other (Specify)								
Peripheral	Peripheral Vascular								
Vessel	Other: Gynecological	_	1 "						

N = new indication; P= previously cleared by FDA via K051541; E=added under Appendix E Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Specification for "Other" Airways, Tracheobronchial tree, Gastrointestinal Tract and Surrounding Other:

Note 2:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Radiological Health

System: Olympus Endoscope for use with Aloka Ultrasound System

Transducer: GF-UCT180

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation								
General	Clinical Application Specific	В	M	PWD	CWD	Color	Combined	Other	
(Track 1 Only)	(Tracks 1 & 3)					Doppler	(Specify)	(Specify)	
Ophthalmic	Ophthalmic							<u> </u>	
	Fetal						<u> </u>		
	Abdominal	P	P	P		P	Note 1		
	Intra-operative (Specify)							ļ <u>.</u>	
!	Intra-operative (Neuro)		_			<u> </u>		<u> </u>	
	Laparoscopic			<del>                                      </del>	<u></u>		<del> </del>	<del> </del>	
	Pediatric			ļ			<del> </del>	<u> </u>	
Fetal Imaging	Small Organ (Specify)				<del>-</del>			-	
& Other	Neonatal Cephalic	<u> </u>	ļ	ļ		<del> </del>	<del></del>		
<b></b> 0	Adult Cephalic		ļ	-		·	<del>                                     </del>	<del>  -</del>	
	Trans-rectal		ļ <u>.</u>				<del> </del>	<u> </u>	
,	Trans-vaginal		<u> </u>	<u> </u>		<del> </del>	<del></del>		
	Trans-urethral			-		P -	Note 1	<del>                                     </del>	
	TEE (non-Cardiac)	P	P	P		<del>  Р</del> —	Note 1		
•	Musculo-skeletal (Convent.)			<del></del>		<del> </del>	<del>                                     </del>	<del> </del>	
	Musculo-skeletal	ļ		·					
	(Superficial)	<u> </u>				<u> </u>	<del>-</del>	<del> </del>	
	Intravascular		· · · ·		<u> </u>	<del> </del>	<del></del>	<del></del> -	
	Intra-luminal		<u></u>	<u> </u>		P -	Note 1	<del> </del>	
	Others (Specify) Note 2	P	P	P		<u> </u>	Note 1	<del> </del>	
	Cardiac Adult		ļ	ļ		<u> </u>		<del> </del>	
	Cardiac Adult, TEE	ļ				ļ			
Cardiac	Cardiac- Neonatal				ļ				
	Cardiac Pediatric, TEE							ļ	
	Intravascular (Cardiac)								
	Other (Specify)						·		
Peripheral	Peripheral Vascular			1				<u> </u>	
Vessel	Other: Gynecological					<u> </u>			

N = new indication; P= previously cleared by FDA K093395; E=added under Appendix E Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: Specification for "Other" Gastrointestinal Tract and Surrounding Organs

Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801 109)

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Division of Radiological Health

Mice of the Vitro Diagnostics and Radiological Health

510(k) K123828

System: Olympus Endoscope for use with Aloka Ultrasound System

Transducer: BF-UC180F

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation								
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)			
Ophthalmic	Ophthalmic		<u> </u>								
	Fetal Abdominal Intra-operative (Specify) Intra-operative (Neuro) Laparoscopic										
Fetal Imaging & Other	Pediatric Small Organ (Specify) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral TEE (non-Cardiac) Musculo-skeletal (Convent.) Musculo-skeletal (Superficial)	P	P	P		P	Note 1				
ļ-	Intravascular Intra-luminal Others (Specify) Note 2	P	P	P		P	Note 1				
Cardiac	Cardiac Adult Cardiac Adult, TEE Cardiac- Neonatal Cardiac Pediatric, TEE Intravascular (Cardiac) Other (Specify)										
Peripheral Vessel	Peripheral Vascular Other: Gynecological										

N = new indication; P= previously cleared by FDA K070983; E=added under Appendix E

Combination of each operating mode includes: Note 1: B/M, B/PWD, B/CD/PWD;

Note 2: Specification for "Other" Airways, Tracheobronchial tree

Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)
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Division of Radiological Health

System: Olympus Endoscope for use with Aloka Ultrasound System

Transducer: TGF-UC180J

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation								
General	Specific	В	M	PWD	CWD	Color	Combined	Other	
(Track 1 Only)	(Tracks 1 & 3)					Doppler	(Specify)	(Specify)	
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal	P	P	P		P	Note 1	ļ. <u></u> .	
:	Intra-operative (Specify)						<u> </u>		
	Intra-operative (Neuro)						<u> </u>		
	Laparoscopic								
•	Pediatric								
E 4 I I continu	Small Organ (Specify)		<u> </u>			ļ	<del></del>	<del>-</del>	
Fetal Imaging & Other	Neonatal Cephalic		_						
& Other	Adult Cephalic							<del> </del>	
	Trans-rectal								
	Trans-vaginal			<u> </u>					
	Trans-urethral	<u></u> .					33 4 3	ļ	
	TEE (non-Cardiac)	P	P	P		· P	Note 1		
	Musculo-skeletal (Convent.)					<u> </u>		ļ	
	Musculo-skeletal					•			
	(Superficial)			4				<del> </del> _	
	Intravascular			<del> </del>					
,	Intra-luminal						Note 1	<del></del>	
	Other (Specify) Note 2	P	P	P		P	Note 1	<del> </del>	
Cardiac	Cardiac Adult		ļ						
	Cardiac Adult, TEE			<u> </u>				•	
	Cardiac- Neonatal				<u></u>				
	Cardiac Pediatric, TEE				<u> </u>				
	Intravascular (Cardiac)								
	Other (Specify)								
Peripheral	Peripheral Vascular								
Vessel	Other: Gynecological	******							

N = new indication; P= previously cleared by FDA K093395; E=added under Appendix E Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

Note 2: Specification for "Other" Gastrointestinal Tract and Surrounding Organs

Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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